



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,666	10/18/2004	Milton L. Brown	00769-07	4259

34444 7590 06/27/2007
UNIVERSITY OF VIRGINIA PATENT FOUNDATION
250 WEST MAIN STREET, SUITE 300
CHARLOTTESVILLE, VA 22902

EXAMINER

OH, TAYLOR V

ART UNIT	PAPER NUMBER
----------	--------------

1625

MAIL DATE	DELIVERY MODE
-----------	---------------

06/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,666

Applicant(s)

BROWN, MILTON L.

Examiner

Taylor Victor Oh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

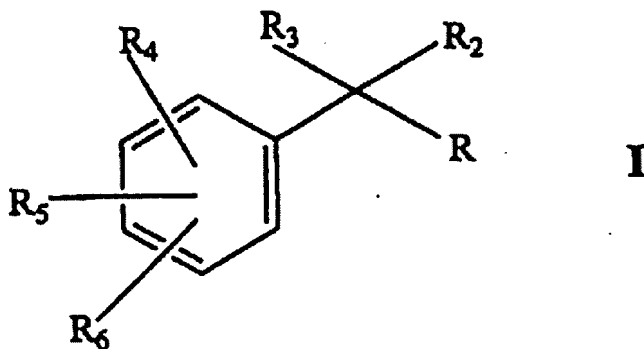
LACK OF UNITY

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2, 4-15, and 19-20 drawn to a non-heterocyclic compound according to the general structure (I):



wherein R is selected from the group consisting of C₁-C₁₂ alkyl, C₂-C₉ alkenyl, C₂-C alkynyl, -(CH₂)_mCOOH, -(CH₂)_mNH₂, -(CH₂)_mCONH₂, -(CH₂)_nC₃-C₆ cycloalkyl, -(CH₂)_naryl, -(CH₂)_nsubstituted aryl, -(CH₂)_pNCH₃(CH₂)_psubstituted aryl and

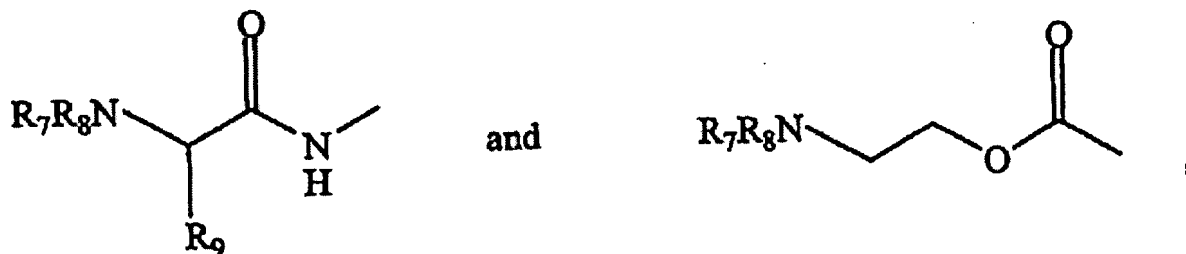
R_2 is selected from the group consisting of $-(CH_2)_nCOOH$, $-(CH_2)_nNH_2$, and $-(CH_2)_nCONHR_{10}$;

R_3 is selected from the group consisting of hydroxy, amino, C_1 - C_4 alkoxy, $-CH_2OH$ and $-CONH_2$,

R_4 and R_5 are independently selected from the group consisting of H, halo, C_1 - C_4 alkyl, C_2 - C_4 alkenyl, C_2 - C_4 alkynyl, and C_1 - C_4 alkoxy; and

R_6 is selected from the group consisting of H, C_1 - C_8 alkyl,

R_6 is selected from the group consisting of H, C_1 - C_8 alkyl,

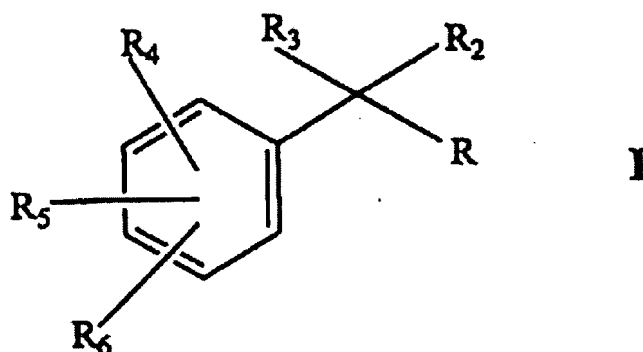


wherein R_7 and R_8 are independently selected from the group consisting of H, C_1 - C_4 alkyl,

C_2 - C_4 alkenyl and C_2 - C_4 alkynyl, and R_9 is H, | R_{10} is selected

from the group consisting of H, benzyl and C_1 - C_4 alkyl,

Group II, claims 1-15 and 19-20 drawn to a heterocyclic compound according to formula (I):



wherein R is selected from the group consisting of

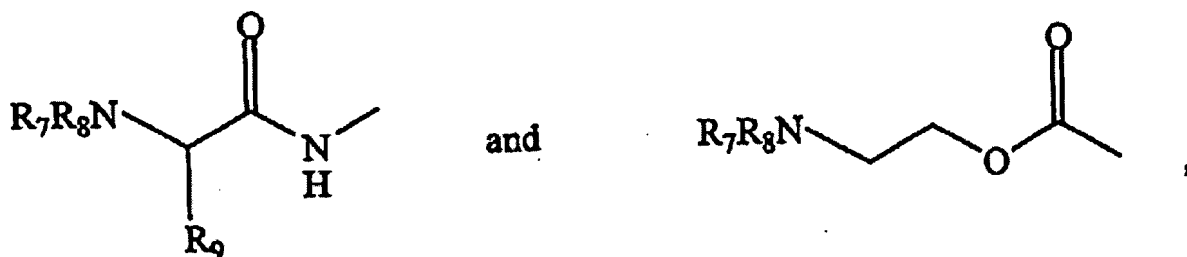
$-(CH_2)_m$ substituted heterocyclic, wherein m is an integer ranging from 3-8, n is an integer ranging from 0-4 and p is an integer ranging from 1-4;

R_2 is selected from the group consisting of $-(CH_2)_nCOOH$, $-(CH_2)_nNH_2$, and $-(CH_2)_nCONHR_{10}$;

: R_2 and R_3 taken together with the atoms to which they are attached form an optionally substituted heterocyclic ring;

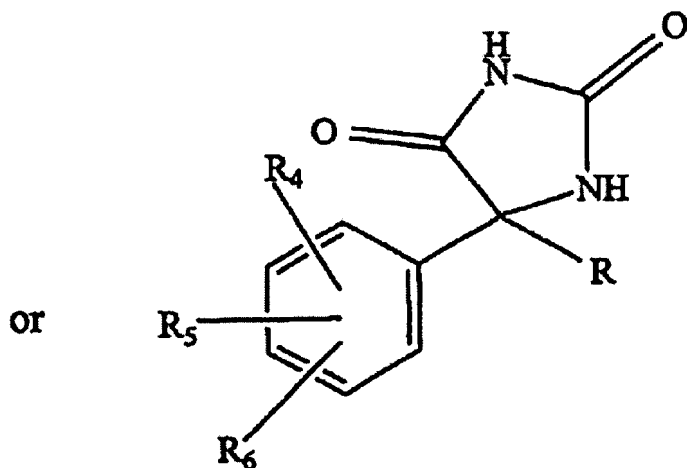
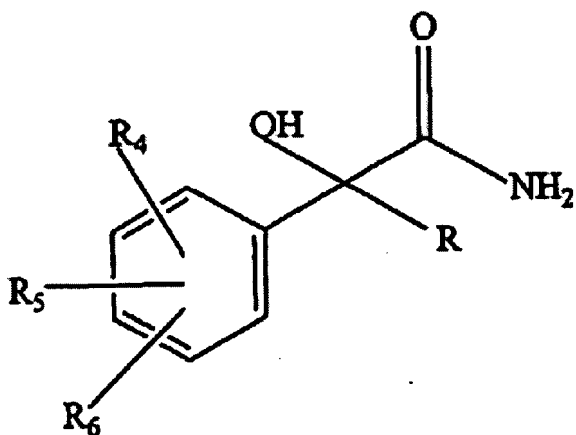
R_4 and R_5 are independently selected from the group consisting of H, halo, C_1 - C_4 alkyl, C_2 - C_4 alkenyl, C_2 - C_4 alkynyl, and C_1 - C_4 alkoxy; and

R_6 is selected from the group consisting of H, C_1 - C_3 alkyl,



wherein R_7 and R_8 are independently selected from the group consisting of H, C_1 - C_4 alkyl, C_2 - C_4 alkenyl and C_2 - C_4 alkynyl, and R_9 is H, or R_8 and R_9 taken together with the atoms which they are attached form an optionally substituted heterocyclic ring, and R_{10} is selected from the group consisting of H, benzyl and C_1 - C_4 alkyl, with the proviso that when R_2 and R_3 taken together form a heterocyclic ring. R is not $-(CH_2)_m$ aryl.

Group III, claim(s) 16-18 drawn to a method of treating a neoplastic disease by administering to a subject in need thereof a composition comprising a compound represented by the general structure:

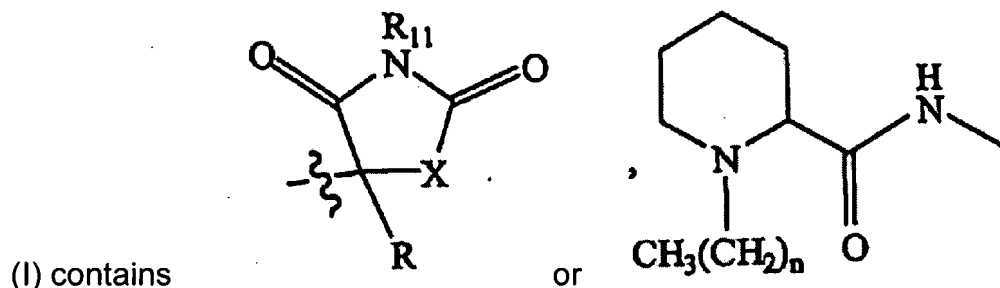


The inventions listed as Group I , Group II ,and Group III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (" requirement of unity of invention ").

PCT Rule 13.2 states "Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In the instant case, the invention of Group I is directed to the non-heterocyclic compound according to formula (I) containing various substituents, such as alkyl, amine, amide, and carboxylic acid in the side branches of the core structure, whereas the invention of Group II is directed to the heterocyclic compound according to formula



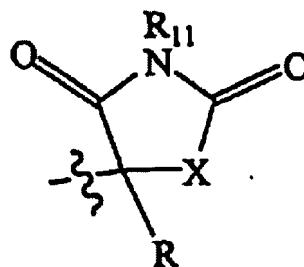
; the hetero group can be attached to the side branches of the core structure. They have different modes of operation, different functions or different effects because each of the non-hetero group and the hetero group has a completely different chemical structure with respect to the core structure. For example, the compound with the hetero group has been known to have a different reactivity or a different effect in comparison

Art Unit: 1625

with the one with the non-hetero group. Therefore, Group I and Group II are unrelated to each other regarding any special technical feature .

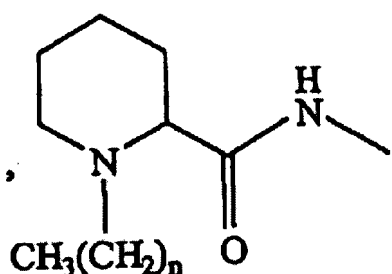
In the instant case , the invention of Group I is directed to the non-heterocyclic compound according to formula (I) contains various substituents ,such as alkyl, amine, amide, and carboxylic acid in the side branches of the core structure, whereas the invention of Group III is directed to the method of treating a neoplastic disease by administering to a subject in need thereof a composition comprising a compound represented by the general structure (I). According to Wu et al (U.S. 6,974,867), the reference discloses a method of treating neoplastic diseases by means of inhibitors of KIAA0175 unlike the means of using the invention of Group I; therefore, the invention of Group I does not require to be present in the method of treating a neoplastic disease as shown in the invention of Group III. Therefore, there is no special technical feature between Group I and Group III.

In the instant case, the invention of Group II is directed to the heterocyclic



compound according to formula (I) contains

or



, whereas the invention of Group III is directed to the method of treating a neoplastic disease by administering to a subject in need thereof a composition comprising a compound represented by the general structure (I). According to Wu et al (U.S. 6,974,867), the reference discloses a method of treating neoplastic diseases by means of inhibitors of KIAA0175 unlike the means of using the invention of Group II; therefore, the invention of Group II does not require to be present in the method of treating a neoplastic disease as shown in the invention of Group III. Therefore, there is no special technical feature between Group II and Group III.

Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

37 CFR 1.475 states that a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combination of categories:

- a. A product and a process specially adapted for the manufacture of said product;
or
- b. A product and a process of use of said product; or
- c. A product, a process specially adapted for the manufacture of the said product,
and a use of the said product; or
- d. A process and an apparatus or means specially designed for carrying out the
said process; or
- e. A product, a process specially adapted for the manufacture of the said product,
and an apparatus or means specially designed for carrying out the said process.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

Art Unit: 1625

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


TAYLOR VICTOR OH
PRIMARY EXAMINER
6/21/07